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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/251,133	02/16/1999	GIRISH V. SHAH	70009590-001	2869

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/251,133

Applicant(s)

SHAH, GIRISH V.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 5-29 is/are pending in the application.
- 4a) Of the above claim(s) 6,8-10 and 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,7 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The examiner of the application has changed. This case has now been transferred as of 3/25/2002. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher Yaen, Group Art Unit 1642.

2. Since applicant has elected Group II, claims 2, 3, and 5 for action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the embodiments of claims 6,8-10 and 22-29, directed to an isolated nucleic acid and DNA, , an expression vector, a recombinant cell, a complex, a method of detecting, method of preparing, and a method of treating have been withdrawn from consideration as being directed to a non-elected invention and an isolated polypeptide comprising SEQ ID No: 2, a composition comprising SEQ ID No: 2 will be examined. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03. Newly submitted claims 6,8-10 and 22-29 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claims are directed to an isolated nucleic acid and DNA, , an expression vector, a recombinant cell, and a complex, which are chemically, structurally, and functionally distinct from the originally claimed invention, which comprises, an isolated polypeptide, a composition wherein the polypeptide is conjugated to a at least one binding agent, and a composition conjugated to a binding agent. In addition, newly added claims are directed to patentable distinct inventions drawn to methods for

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detecting, preparing, and treating, which requires a separate search from the one already performed in the first office action. These claims are distinct and are not examined because they are drawn to subject matter not disclosed in the originally presented claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 6,8-10 and 22-29 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Claims 2, 3, 5, and newly added claims 7,11-21 are examined in the merits.

Claim Rejections Withdrawn - 35 USC § 112

3. The rejections of claim 2, 3, and 5 under 35 USC§112, second paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant refers as the invention is **withdrawn**, in view of the amended claim language.

4. The rejection of claims 2, 3, and 5 under 35 USC§112, first paragraph as containing subject matter that was not described in the specification in such a way as to convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention, is **withdrawn** in view of the amended claim language.

Claim Rejections Withdrawn - 35 USC § 101

5. The rejection of claim 2 under 35 USC § 101 because the invention was directed to non-statutory subject matter is **withdrawn**, in view of the amended claim language.

Claim Rejections Maintained- 35 USC § 112

6. The rejection of claims 2, 3, and 5 under 35 USC§112, first paragraph as containing subject matter that was not described in the specification in such a way as to convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention, is **maintained**, the arguments set forth by the applicant were considered but not found persuasive for the following reasons. Applicant amended claims to recite "*a[n] isolated polypeptide, comprising an amino acid sequence of SEQ ID No: 6*", such is not seen as sufficient to provide to one of skill in the art the adequate written description of the claimed invention. As stated in prior office action, the NEM peptide (SEQ ID No:1) described in the specification shows no relation to the polypeptide of SEQ ID No: 6. In addition, it is stated in the specification that peptide SEQ ID No: 6 are "*alternative sequences based on cDNA SEQ ID depending on the reading frame employed to translate*",(see specification pg 8 3rd paragraph) furthermore, the cDNA aside from that actually isolated (SEQ ID No: 2) is a derived sequence, not an actual isolation (see specification pg 8 , 2nd & 3rd paragraph). Therefore, the specification has not indicated to those of skill in the art that at the time of the invention, applicant was in possession claimed invention.

Claim Rejections Maintained- 35 USC § 101

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7. The rejection of claim 2,3, and 5 under 35 USC§101 because the invention is directed to non-statutory subject matter, is **maintained**. Applicant's arguments are not found persuasive for reasons of record and because of the following reasons. Applicant argues that the cDNA was isolated from prostate cancer, subcloned into vector, then the plasmid containing NEM cDNA was transfected in prostate cancer cell lines PC-3M cells to produce the novel NEM polypeptide (see Response to Office Action Paper No. 20, pg 8 lines 9-15). Applicant also asserts that that the utilities set forth for the NEM peptide disclosed in the specification can be attributed to other peptides, and not to any particular SEQ ID (see specification pg 8 last line). In response to the arguments set forth by the examiner, the applicant also states that *"the specification supports a credible, substantial and specific utility for any of the disclosed sequences, including SEQ ID No: 6."* (see Response to Office Action pg 9 line 12). Lastly, the applicant states, that since the findings of the instant application are drawn to a *"novel protein"*, there is no correspondence to any already identified protein or to any protein of the prior art.

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As stated in the prior office action, because the NEM protein of SEQ ID No: 1, disclosed in the instant application shows no structural overlap or identity to the that of SEQ ID No: 6, one can not assert that the utilities that apply for those disclosed on the instant application for SEQ ID No: 1 can be applied to a protein that is not structurally the same or similar. In addition, because SEQ ID No: 6 is a derived sequence, there is no evidence that the biological effects and activities are similar to those of SEQ ID No: 1 and thus utilities applied to SEQ ID No: 1 may not apply to those of SEQ ID No: 6. ,

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Furthermore, because the discovery of SEQ ID No: 1 is claimed to be novel, any derived sequence from this discovery must have an associated structure, function, and utility. The instant application has not disclosed any specific information on structural relationship between SEQ ID No: 1 and 6 and has not disclosed any specific function or utility for SEQ ID No: 6. Because there is an absence of this information, the invention is not supported by any specific utility, or any well established utility.

The rejection of 2,3, and 5 rejected under 35 USC §112, first paragraph, for not being supported by either a substantial or specific utility or a well established utility, wherein one skilled in the art would not know how to use the claimed invention, is **maintained** for the reasons on record. The arguments set forth by the applicant are not found persuasive for the following reasons. For the same reasons given above for 35 USC §101, the applicant has not enabled to one of skill in the art the necessary information to make and use the claimed invention. The instant application has only provided to one of skill in the art the necessary information to make and use the peptide of SEQ ID No: 1. Applicant argues that several samples were isolated and 4 nucleotide sequences were derived, of which 8 amino acid sequences were derived (see Response to Office Action pg 10 last paragraph). There is no expression data or any evidence found in the specification that would lead one of skill in the art to know whether SEQ ID No: 6 is actually expressed and whether this peptide can actually be used for the asserted utilities of that disclosed for SEQ ID No: 1. Because there is a lack an enabling disclosure for SEQ ID No: 6, one skilled in the relevant arts would be forced into undue experimentation.

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⁶ Because newly added claims 11-15 are dependent on claims 2 or 3, and the rejections set forth above have not been overcome, these claims are also rejected under 35 USC§ 112, first paragraph and 35 USC§101.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

⁶ A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

⁶ Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
May 18, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600